REMARKS

Summary of the Amendments

By the foregoing amendment, non-elected claims 1-30 are canceled without prejudice or disclaimer and preserving Applicants' right to file a divisional application and continuation applications including the non-elected invention; claims 31-34, 36, 37, 41, 44-46 and 48-50 are amended, and claims 51-59 are added, whereby claims 31-34, 36, 37 and 39-59 remain pending.

Claims 39-47 stand withdrawn from consideration as being drawn to a non-elected invention.

The claims have been amended herein to be more in accordance with idiomatic English and standard U.S. practice, and claim 31 has been amended as will be discussed below with respect to the 35 U.S.C. 112, second paragraph, rejection. Moreover, independent claim 51 has been added directed to the combination of cell culture carriers to which cells can adhere to and grow on surfaces thereof, and a cell culture apparatus for use with the cell culture carriers, and claims have been amended to be dependent directly or indirectly upon independent claim 51.

Any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Statement Of Telephone Interview

Applicants express appreciation for the courtesies extended by Examiner Singh during a telephone interview on October 19, 2007. During this telephone interview, Applicants' representative Arnold Turk indicated that Applicants were considering filing a Request for

Continued Examination including combination claims directed to cells culture carriers recited in claim 31 in combination with a cell culture apparatus recited in claim 39. Applicants' representative also indicated that the combination claims may be presented either with or without maintaining one or more claims directed to cell culture carriers.

The Examiner indicated the filing of a combination claim as proposed including cell culture carriers therein would be directed to the elected subject matter, and would be appropriately examined in a Request for Continued Examination.

Restriction Requirement

Applicants note that claims 1-30 and 39-47 remain withdrawn from consideration by the Examiner as being directed to non-elected inventions.

By the amendment herein, Applicants are canceling non-elected claims 1-30 while preserving their right to file divisional and continuation applications.

Moreover, Applicants submit that newly-added claims 51-59 are examinable with the elected subject matter as indicated by the Examiner during the above-noted telephone interview.

Still further, Applicants submit that withdrawn claims 39-47 should be rejoined with the elected subject matter, because the subject matter of independent claim 39 is presently included with the elected claims which include a combination as recited in independent claim 51.

Claim of Foreign Priority

Applicants express appreciation for the acknowledgement of Applicants' claim of priority and receipt of the certified copy of the Japanese priority application.

RESPONSE TO REJECTIONS

1. Response to Rejections under 35 U.S.C. § 112, second paragraph

Claims 31-34, 36, 37 and 48-50 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Office Action submits that the phrase, "a coating layer containing a calcium phosphate-based compound as a **main component** thereof" (emphasis in the rejection) recited in claim 31 is ambiguous. Moreover the Office Action submits that the same phrase, "a coating layer containing a calcium phosphate-based compound as **a** main component thereof" (emphasis in the rejection) recited in claim 31 is ambiguous.

In response, and without expressing any agreement or acquiescence with the rejections of record, Applicants have amended claim 31 to recite "a coating layer containing a calcium phosphate-based compound".

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. 112, second paragraph, rejection.

Response to Rejections under 35 U.S.C. 103(a)

The Office Action rejects claims 31-34, 36, 37 and 48-50 under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,210,715 to Starling et al. (hereinafter "Starling") or U.S. Pat. No. 5,540,995 to Kitano et al. (hereinafter "Kitano") in view of GB 2,093,040A to Nilsson et al. published as WO 82/00660 (hereinafter "Nilsson").

The Office Action submits that Starling discloses, among other things, cell culture carriers to which cells are allowed to adhere to and grow on surfaces thereof, wherein each of the carriers comprising glass or polymeric beads, but does not explicitly teach cell culture carrier comprising a magnetic particle in combination with a polymeric resin material.

The Office Action submits that Kitano discloses, among other things, granular polymer composites comprising polymer beads having coated on the surface thereof a calcium phosphate-based compound, but does not explicitly disclose a magnetic particle in combination with a polymeric resin material

The Office Action submits that Nilsson discloses, among other things, cell culture carriers comprising a magnetic particle having a surface, and a coating layer of gelatin or chitosan polymers.

In view of the teachings of the cited documents, the rejection asserts that it would have been obvious to incorporate the magnetic particles of Nilsson into the polymeric microbeads or cell culture composition of Starling or Kitano, "such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof."

The Office Action contends that Applicants' arguments filed May 8th 2007 are not persuasive. The Office Action contends that the instant claims are generally directed to cell culture carriers (useful for anchorage-dependent cell cultivation; product-by-process claims) comprising a magnetic particle having a base body with a surface (the base body formed by compounding a resin material and a magnetic material so that the magnetic material is dispersed in the resin); and a coating layer containing a calcium phosphate-based compound as the main component, the coating layer being provided to cover at least a part of the surface of the base body of the magnetic particle.

The Office Action contends that:

> The cited prior art references (Starling et al, or Kitano et al in view of Nilsson et al) relied upon by the Examiner in the obviousness rejection of record (see also discussion above) disclose various cell culture carriers (in the form of microbeads, or microcarriers; suitable for attachment of cells and for anchorage-dependent cell

> cultivation) that can be formed of polymeric beads (such as resin materials) and can be coated with porous, calcium phosphate-based compound, that can be modified (in view of Nilsson et al) to include a magnetic material (as Nilsson et al disclose the benefits of incorporating magnetic particles in the microcarriers such as permitting the use of external magnetic field to stir, suspend and/or isolate the microcarriers; see Nilsson et al, abstract, in particular). Since, all the elements of the claimed invention are disclosed in the prior art including the process of compounding a resin material or polymeric beads with porous CaP particles (see Kitano et al, use of Nara Hybridization system to incorporate a coating layer of CaP; column 5 2nd paragraph, and examples 1-7, in particular) that can be likewise used by one of ordinary skill in the art for incorporating the magnetic material, and thus for successfully modifying the cell culture carriers disclosed by Starling et al or Kitano et al. In the absence of any evidence to contrary, the cell culture carriers disclosed by the prior art references (Starling et al or Kitano et al in view of Nilsson et al) meet all the limitations of the instant invention as claimed, and therefore, the obviousness rejection of record over the pending claims is properly maintained.

Applicants submit that the question is not whether the prior art discloses parts of Applicants' claimed subject matter, but whether one having ordinary skill in the art following the prior art utilized in the rejection would arrive at Applicants' claimed subject matter following the prior art. Under the present circumstances, one having ordinary skill in the art would not arrive at, as recited in Applicants' independent claim 31, cell culture carriers to which cells can adhere to and grow on surfaces thereof, each of the cell culture carriers comprising a magnetic particle having a base body having a surface, the base body being formed by compounding a resin material and a magnetic material so that the magnetic material is dispersed in the resin material; and a coating layer containing a calcium phosphate-based compound, the coating layer being provided to cover at least a part of the surface of the base body of the magnetic particle so that the cells can adhere thereto.

The Examiner's attention is once again directed, for example, to Applicants' originally filed specification, at page 5, last paragraph, wherein it is disclosed that:

> Further, in this embodiment, it is preferred that each of the magnetic particles is formed by compounding a resin material and a magnetic material. According to

> this method, it is possible to adjust a density (specific gravity) of the magnetic particle (consequently, the cell culture carrier) by setting compounding ratio (mixing ratio) between the resin material and the magnetic material appropriately. Further, the shape and size of the cell culture carrier can also be adjusted easily.

Still further, reference is once again made to Applicants' originally filed specification beginning at page 36, penultimate for further description of the preferred magnetic particle being formed of a composite material which is obtained by compounding a resin material and a magnetic material.

Applicants submit that the Office Action fails to provide sufficient arguments to combine Starling or Kitano and Nilsson, including why these documents should be combined to arrive at the presently claimed subject matter.

For example, as once again stated in the Office Action, both of the primary documents of Starling and Kitano fail to disclose a cell culture carrier comprising a magnetic particle. Moreover, while the Office Action submits that the secondary document of Nilsson discloses magnetic particles, there is no reason to arrive at Applicants' recited subject matter following any combination of these documents.

Thus, Applicants respectfully submit that the reasoning set forth in the Office Action, *i.e.*, "such that the cell culture carriers have a magnetic particle having a surface, and a coating layer formed of porous, particulate CaP-based compound so that the cells are allowed to adhere to the surface thereof" is insufficient motivation to establish a *prima facie* case of obviousness for the combination recited in Applicants' claim 31.

Still further, regarding newly added combination claims 51-59 and amended combination claims 32-34, 36, 37 and 48-50, Applicants submit that the combination recited in independent claim 51 and further defined in the dependent claims provides various combinations that are not taught or suggested by any of the documents utilized in the rejection, whether taken alone or

together. Since the cell culture carriers recited in claim 51 are in combination with the cell culture apparatus having the cell culture vessel and the magnetic filed generator, the cell culture carriers can be uniformly suspended in a culture solution due to the application of the magnetic field, such as disclosed in Applicants' originally filed specification at page 35, second paragraph. Therefore, it becomes easy for cells to adhere to the surfaces of the cell culture carriers, and nutrition can be equally supplied to the cells adhering to the cell culture carriers (see Applicants' specification at page 35, third paragraph). As a result, cells can grow more efficiently (see Applicants' specification at page 36, lines 5-6).

In contrast, Nilsson, Starling and/or Kitano fail to disclose the cell culture carriers and/or the cell culture apparatus as recited in independent claim 51 or further defined in the dependent claims. At most, Nilsson discloses at page 6, lines 24-27, that, "it is conceivable to suspend the beads by applying an outer magnetic filed, thereby minimizing the need for vigorous agitation when using carriers of high specific weight." There is no teaching or suggestion of the advantages associated with Applicants' claimed subject matter and/or providing a combination including the structural features recited in Applicants' claims.

Still further, the dependent claims are patentable for at least the reasons set forth above, and for the additional features recited therein.

Accordingly, for at least the foregoing reasons, the 35 U.S.C. § 103 rejection of claims 31-38 over Starling or Kitano in view of Nilsson should be withdrawn.

2. Response to Obviousness-Type Double Patenting Rejection

The Office Action provisionally rejects claims 31-34, 36, 37 and 48-50 on the grounds of obviousness-type double patenting as being unpatentable over claims 1-11 of copending application No. 11/190,868 ("Ishikawa").

Applicants respectfully request withdrawal of the obviousness-type double patenting rejection in view of the following remarks.

Applicants respectfully submit that the Office Action does not set forth a sufficient basis for asserting that the claims of the instant application are obvious over the claims of Ishikawa. For example, the rejection merely asserts that the claims are co-extensive, but does not indicate the differences between the claims, nor does the rejection include what is considered to be an obvious difference.

Moreover, Applicants note that because the rejection is provisional, the present application can be past to issue, with a double patenting rejection, if deemed appropriate by the Examiner, being made in the other application.

Still further, obviousness-type double patenting rejection should not be applicable to the combination claims which include cell culture carriers in combination with cell culture apparatus.

The Examiner is once again requested to contact the undersigned if the only item preventing the allowance of the claims is the filing of a Terminal Disclaimer to overcome the obviousness-type double patenting rejection over Application No. 11/190,868.

Therefore, in view of the foregoing, Applicants respectfully request withdrawal of the obviousness-type double patenting rejection.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully requests that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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